Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892.

Open: January 19, 2001, 8:30 a.m. to adjournment.

Agenda: Presentation of NIMH Director's Report and discussion of NIMH program and policy issues.

Place: National Institute of Health, 9000 Rockville Pike, Building 31, Conference Room 6, Bethesda, MD 20892.

Contact Person: Jane A. Steinberg, PHD, Director, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–5047.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: December 4, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–31520 Filed 12–11–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Mental Health; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b((c)(6), Title 5 U.S.C., as amended. The contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel.

Date: December 18, 2000.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: Neuroscience Center, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Michael J. Moody, Scientific Review Administrator, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6154, MSC 9609, Bethesda, MD 20892–9609, 301–443–3367.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281, Scientist Development Award, Scientist Development Award for Clinicians, and Research Scientist Award; 93.282, Mental Health National Research Service Awards for Research Training, National Institutes of Health, HHS)

Dated: December 4, 2000.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 00–31521 Filed 12–11–00; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Proposed Actions Under the NIH Guidelines

AGENCY: National Institutes of Health (NIH), PHS, DHHS.

ACTION: Notice of proposed actions under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

SUMMARY: The NIH is proposing changes to the NIH Guidelines to enhance its oversight of human gene transfer research by making modifications to the reporting and analysis of serious adverse events in human gene transfer research studies. The purpose of this Notice is to inform the public about the proposed changes and to seek public comment on them. The proposed changes involve four main issues: (1) The scope and timing of serious adverse event reporting; (2) public access to information about serious adverse events; (3) protection of individually identifiable patient information as it relates to serious adverse event reporting; and (4) a new mechanism for the review and assessment of data on serious adverse events and other relevant safety information.

The NIH currently requires all serious adverse events to be reported immediately whether or not they are expected or considered to be associated with the gene transfer product. The first proposed change would require expedited reporting for those serious adverse events that are unexpected and considered possibly associated with the use of the gene transfer product. The proposed change also provides timeframes for expedited reporting and definitions of serious, associated, and unexpected adverse events. Under this proposal, other reportable serious adverse events would be included in annual reports.

The second proposed change would clarify that serious adverse event reports submitted to the NIH may not be classified as confidential information and that trade secret or other commercial confidential information should not be included in serious adverse event reports.

The third proposed change adds specific language to the NIH Guidelines to prohibit the submission of individually-identifiable patient information in serious adverse event reports.

The fourth and final change is the establishment of a working group of the NIH Recombinant DNA Advisory Committee (RAC), to be known as the NIH Gene Transfer Safety Assessment Board, that will be responsible for the review and analysis of serious adverse event reports and other relevant safety information in gene transfer research studies. The working group will report safety information to the RAC and information will, thereby, be disseminated to the scientific and patient communities and the public.

DATES: The public is encouraged to submit written comments on these proposed changes. Comments may be submitted to NIH Office of Biotechnology Activities (OBA) in paper or electronic form. Comments received on or before February 10, 2002 will be reproduced and distributed to the RAC for consideration at a future meeting to be announced.

All comments received in response to this notice will be considered by the NIH and will be available for public inspection in the NIH OBA office weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION: If you have questions, or require additional information about these proposed changes, please contact OBA by e-mail at oba@od.nih.gov, or telephone at 301–496–9838. Comments can be submitted to the same email address or by fax to 301–496–9839 or mail to the Office of Biotechnology Activities, National Institutes of Health, Building 1, Room 103, Bethesda, Maryland 20892.

For additional information about the RAC meeting at which these proposed changes will be deliberated, please visit the NIH/OBA Web site at: *http://www.nih.gov/od/oba/.*